

REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

Claims 1-22 were pending in this application when last examined and stand rejected.

Claims 5, 12, 14-15 and 22 are cancelled without prejudice or disclaimer thereto.

Claims 1, 6-11, 13, 16 and 19-21 are amended to clarify the claimed invention. No new matter has been added. Support for new claims 23-26 can be found in the claims as filed.

The Examiner is respectfully requested to acknowledge the claim made to foreign priority by checking the appropriate boxes in item 12 of the cover sheet of the next Office Action.

On page 2, the Disclosure was objected to for incorporating by reference provisional application No. 60/608,104. Applicants respectfully disagree with this objection. In particular, attached herewith (Attachment A) is the Claim for Priority in this application as well as a PCT document showing that priority was recognized by the International Bureau. Finally, this attachment shows a Declaration showing that priority was claimed in this application to a provisional application. Thus, the Claim for Priority is perfected and incorporation by reference to the provisional application should be proper.

Also on page 2 of the Office Action, claims 13 and 17-20 were objected to for the noted informalities. This objection is overcome, as applied to the amended claims, for reasons which are self-evident.

On pages 2-3 of the Office Action, claims 1-22 were rejected under 35 U.S.C. 112, second paragraph, as indefinite. This rejection is overcome, as applied to the amended claims, for reasons which are self-evident.

On pages 3-5, claims 1-6, 8-13, 15-16 and 21-22 were rejected under 35 U.S.C. 102(e) as being anticipated by Bonnerjea et al (WO 2004/076485). This rejection is respectfully traversed as applied to the remaining amended claims.

It is noted that claims 1 and 13, the only independent claims under examination, are amended to further define fractionating into at least two fractions and wasting the tail fraction. Such limitation was previously presented in claims 7 and 14, which were not part of this

rejection. Further, it appears that the last full paragraph on page 4 of the Office Action indicates that such limitation is not taught by Bonnerjea. Thus, this rejection is overcome.

On pages 5-9, claim 1-6, 8-13 and 21 were rejected under 35 U.S.C. 103(a) as being obvious over JP 7-155194 A in view of Racher et al. and, as necessary, EP 0,284,268 . Applicants respectfully traverse this rejection as applied to the remaining amended claims.

Initially, it is again noted that claims 1 and 13, the only independent claims, have been amended to include the limitations of claims 7 and 14 which were not subject to this rejection. Thus, this rejection is overcome. Further, Applicants herein provide the following remarks.

The examiner acknowledges that the '194 reference does not teach the removal of aggregated antibody after the anion exchange step. The Examiner further argues that Racher et al. teaches a SEC step following anion exchanger to remove aggregates.

Accordingly, since the present invention teaches a simplified method, i.e. that aggregate removal can surprisingly and efficiently be achieved by fractionation of the ion exchange flow through fraction into at least two fractions followed by discarding / wasting the tail fraction, it is respectfully submitted that the claimed invention is not obvious over the art cited by the Examiner.

Finally, on pages 8-9, claim 17 was rejected under 35 U.S.C. 103(a) as obvious over the above-noted references and further in view of Wan et al. (US 6,177,548). Applicants respectfully traverse this rejection. It is again noted that this rejection does not include claims 7 and 14, the limitations which have been added to the independent claims. Thus, this rejection is overcome.

In particular, the Examiner alleges that claims 1-3, 12, 15 and 16 are obvious over Wan et al. who show the separation of antibody monomers from aggregates by anion exchange chromatography wherein the aggregate bind to the anion exchanger. Since the invention claimed in the amended set of claims teaches that discarding of aggregated antibodies in the tail fraction of the flow through of an ion exchanger, it is respectfully submitted that the claimed invention is not obvious over Wan et al.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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